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| APPLICATION NO.   | FILING DATE    | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|---|----------------|----------------------|-------------------------|------------------|
| 09/495,556  | 02/01/2000     | Eric H. Kuhrts       | -                       | 5012             |
| 7   | 590 04/23/2002 |                      |                         |                  |
| JAMES W. COLLETT, PH.D.<br>SHELDON & MAK<br>225 SOUTH LAKE AVENUE |                |                      | EXAMINER                |                  |
|   |                |                      | DI NOLA BARON, LILIANA  |                  |
| 9TH FLOOR<br>PASADENA, CA 91101                                   |                |                      | ART UNIT                | PAPER NUMBER     |
| •   |                |                      | 1615                    |                  |
|   |                |                      | DATE MAILED: 04/23/2002 | 45               |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <del></del>   |   | Application No.          | Applicant(s)   |  |  |  |
|---|---|--------------------------|--|--|--|--|
| Office Action Summary   |   | 09/495,556               | KUHRTS, ERIC H.                                      |  |  |  |
|   |   | Examiner                 | Art Unit   |  |  |  |
|   |   | Liliana Di Nola-Baron    | 1615   |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address   |   |                          |  |  |  |  |
| Period for Reply  |   |                          |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                          |  |  |  |  |
| Status<br>1)⊠   | Paspansive to communication(s) filed on 27  | Fohruani 2002            |  |  |  |  |
| اکار<br>(2a   | Responsive to communication(s) filed on <u>27</u> .  This action is <b>FINAL</b> . 2b)  | nis action is non-final. |  |  |  |  |
| 3)□   | <b>/—</b>   |                          | rosecution as to the marite is                       |  |  |  |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims   |   |                          |  |  |  |  |
| 4)⊠ Claim(s) <u>51-105</u> is/are pending in the application.   |   |                          |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |                          |  |  |  |  |
| 5) Claim(s) is/are allowed.   |   |                          |  |  |  |  |
| 6)⊠ Claim(s) <u>51-105</u> is/are rejected.   |   |                          |  |  |  |  |
| 7)  | 7) Claim(s) is/are objected to.   |                          |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |                          |  |  |  |  |
| Application Papers  |   |                          |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |                          |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |   |                          |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                          |  |  |  |  |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.  |   |                          |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |                          |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |   |                          |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120  13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  |   |                          |  |  |  |  |
| a) ☐ All b) ☐ Some * c) ☐ None of:  |   |                          |  |  |  |  |
| 1.☐ Certified copies of the priority documents have been received.  |   |                          |  |  |  |  |
| 2. Certified copies of the priority documents have been received in Application No  |   |                          |  |  |  |  |
| Copies of the certified copies of the priority documents have been received in this National Stage  |   |                          |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.   |   |                          |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |   |                          |  |  |  |  |
| <ul> <li>a) ☐ The translation of the foreign language provisional application has been received.</li> <li>15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</li> </ul>  |   |                          |  |  |  |  |
| Attachment(s)   |   |                          |  |  |  |  |
| 2) Notice   | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) _ | 5) Notice of Informal I  | r (PTO-413) Paper No(s) Patent Application (PTO-152) |  |  |  |

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## **DETAILED ACTION**

Receipt of Applicant's amendment, filed on February 27, 2002, is acknowledged.

## Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 51-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandralis et al.

The claimed invention refers to microencapsulation processes and pharmaceutical composition comprising a microencapsulated core material.

Mandralis et al. provides a process for encapsulating a core material comprising mixing a core material in a water/polymer system with a fat phase at a temperature higher than the melting temperature of the fat, stirring to reach the desired droplet size and rapidly cooling, so that the fat phase solidifies before the emulsion droplets are allowed to coalesce (See e.g., col. 3, lines 19-29). Mandralis et al. teaches that the core may be used in the food industry or may be a pharmaceutical and the polymer may be a polysaccharide (See e.g., col. 2, lines 23-42). Mandralis et al. includes hydrogenated soybean oil among the fats used in the invention (See e.g., col. 3, lines 36-46).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Mandralis et al. to device methods of microencapsulation and compositions comprising a microencapsulated core. Because of the teachings of Mandralis et al., that by raising the temperature of the system above the fat melting point the spherical capsules can be separated from the fat phase, one of ordinary skill in the art would have a reasonable expectation that the processes claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

## Response to Arguments

3. Applicant's arguments with respect to claims 30-50 have been considered but are moot in view of the new ground(s) of rejection.

## Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/1235.

April 21, 2002

Gollamudi S. Kishore, PhD

**Primary Examiner** 

Group 1500